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UNITED STATES PATENT AND TRADEMARK OFFICE

RESPONSE UNDER RULE 116

EXPEDITED HANDLING PROCEDURES

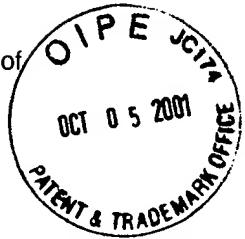
In re Patent Application of

Elmore

Serial No. 08/981,087

Filed: May 27, 1998

Title: TYPE F BOTULINUM TOXIN AND USE THEREOF



Atty Dkt. 1498-133

C#/M#

Group Art Unit: 1647

Examiner: Turner

Date: October 5, 2001

OCT 10 2001

TECH CENTER 1600/2900

RECEIVED

Assistant Commissioner for Patents

Washington, DC 20231

BOX AF

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

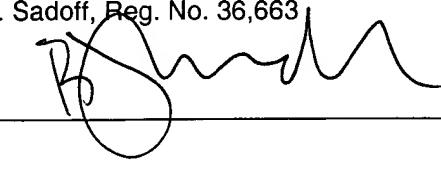
Fees are attached as calculated below:

| | | | | |
|--|----|----------------------|---------------------------|------------------|
| Total effective claims after amendment | 0 | minus highest number | | |
| Previously paid for | 20 | (at least 20) = | 0 x \$ 18.00 | \$ 0.00 |
| Independent claims after amendment | 0 | minus highest number | | |
| Previously paid for | 3 | (at least 3) = | 0 x \$ 84.00 | \$ 0.00 |
| If proper multiple dependent claims now added for first time, add \$280.00 (ignore improper) | | | | \$ 0.00 |
| Petition is hereby made to extend the current due date so as to cover the filing date of this Paper and attachment(s) (\$110.00/1 month; \$400.00/2 months; \$920.00/3 months) | | | | \$ 110.00 |
| Terminal disclaimer enclosed, add \$ 110.00 | | | | \$ 0.00 |
| <input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$740.00) | | | | \$ 0.00 |
| <input type="checkbox"/> Please enter the previously unentered , filed | | | | |
| <input type="checkbox"/> Submission attached | | | | |
| | | | SUBTOTAL | \$ 110.00 |
| If "small entity," then enter half (1/2) of subtotal and subtract | | | | -\$ 0.00 |
| <input type="checkbox"/> Applicant claims "small entity" status. <input type="checkbox"/> Statement filed herewith | | | | |
| Rule 56 Information Disclosure Statement Filing Fee (\$180.00) | | | | \$ 0.00 |
| Assignment Recording Fee (\$40.00) | | | | \$ 0.00 |
| Other: | | | | 0.00 |
| | | | TOTAL FEE ENCLOSED | \$ 110.00 |

The Commissioner is hereby authorized to charge any deficiency in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
 By Atty.: B. J. Sadoff, Reg. No. 36,663

Signature: 



UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Expedited handling
Response after final rejection

TECH CENTER 1600/2900

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10/10/01

ELMORE

Atty. Ref.: 1498-133

Serial No. 08/981,087

Group: 1647

Filed: May 27, 1998

Examiner: Turner, S.

For: TYPE F BOTULINUM TOXIN AND USE THEREOF

October 5, 2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

REQUEST FOR RECONSIDERATION OF PETITION
DECISION MAILED AUGUST 10, 2001

Responsive to the PETITION DECISION mailed August 10, 2001, reconsideration is requested along with consideration and entry of the attached Second Amendment Under Rule 116, and allowance of the pending claims.

Claims 3-28 and 30-33 are pending. Claims 13-18 and 25 have been withdrawn from consideration. Claims 3, 4, 20, 22, 23, 24 and 27 have been canceled, without prejudice, to advance prosecution in the attached Second Amendment Under Rule 116. Accordingly, upon entry of the attached Amendment, claims 5-19, 21, 25, 26 and 28-33 will be pending. Entry of the attached Amendment will, at a minimum, reduce the issues for any possible appeal, for the reasons described in the attached. Entry of the attached Amendment therefore is requested.

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The attached Second Amendment presents the same amendments and remarks as the Amendment filed September 5, 2001, with additional amendments to claim 8 to include an "and" to recite a more traditional Markush group, and to amend claims 13-18 and 25 to be dependent on what the applicants submit are allowable protein claims and in support of the present Request for Reconsideration of the PETITION DECISION.

Reconsideration and withdrawal of the restriction requirement is again requested. The applicants traversed the restriction requirement and requested reconsideration of the same in their response of September 14, 1999. The restriction requirement was maintained in the Examiner's Action of October 7, 1999. The applicants filed a Petition under Rule 181 on January 7, 2000, for the Commissioner to invoke his supervisory authority to have the restriction requirement withdrawn. The applicants requested, in the interest of efficient prosecution, consideration of the Petition prior to further action on the merits. Contrary to the applicants request, a further Action on the merits was issued March 16, 2000. A reply to the Action of March 16, 2000, was filed June 16, 2000, which included a request for a Decision on the Petition. A supplemental amendment was filed June 19, 2000. A Status Request was filed December 19, 2000. A Notice to Comply was mailed February 27, 2001, and a Response to the Notice to Comply was filed March 27, 2001. A further Action on the merits, which is a final rejection, was mailed June 5, 2001. The Examiner acknowledged the Petition in the final Office Action and advised the applicants to contact the Examiner or Mr. Kunz if a Decision was not received "**in a timely fashion**". A Decision on the applicants' Petition filed January 7, 2000, was mailed August 10, 2001, i.e., 18 months after filing the

Petition and after the issuance of three further papers and a final rejection by the Patent Office. The Decision denied the applicants' Petition, and set a two-month period for requesting reconsideration. The Request for Reconsideration is being filed to again request withdrawal of the restriction requirement.

The undersigned submits, with all due respect, that the failure of the Patent Office to timely respond to the applicants' Petition of January 7, 2000, has been prejudicial to the applicants as, at least, the applicants must now pay for a one month extension to amend the claims in support of the attached Request for Reconsideration. Had the Patent Office mailed a Decision on the Petition prior to issuance of the final rejection, the applicants would not have been required to pay for further extensions to further amend the claims. A Refund Request is therefore attached requesting refund of the attached one month extension fee.

The applicants submit that, pursuant to Rule 116(c), the attached Amendment, at least with regard to claims 13, 14 and 17, are necessary to place claims 13-18 and 25 in condition for allowance and in condition to define a special technical feature in common with the remaining claims which are under active consideration. Moreover, the amendments were not previously made as the amendments have been made in response to the Petition Decision dated August 10, 2001. Entry of the Amendment is requested and submitted to comply with the requirements of Rule 116(c).

In the event the above attached Amendment is not entered, withdrawal of the finality of the Office Action of June 5, 2001 is requested as the applicants Petition of January 7, 2000, had not yet been decided prior to issuance of the final rejection.

Accordingly, issues relating to the merits of the patentability of the claims and the scope of the patentably distinct inventions, according to the U.S. Patent Office's interpretation of the requirements for Unity of Invention, were outstanding when the final Office Action was mailed on June 5, 2001.

Withdrawal of the restriction requirement is again requested as, upon entry of the attached Amendment, the pending claims define a single invention.

That is, the Decision asserts that the holding of Lack of Unity is based on the

"... evidence that the polypeptide is known and thus does not make a contribution over the art. As evidence that the polypeptide does not make a contribution over the art, the article in Current Microbiology [i.e., East et al, Current Microbiology, 29, 69-77 (1994)] is initially cited." See, page 3 of the Petition.

At the time the Decision was mailed by the Patent Office however, the Examiner had indicated that the claims of the elected polypeptide defined patentably over the "Current Microbiology" reference. The Examiner continued to reject however certain of the claims defining the subject matter of the elected polypeptide as allegedly being anticipated by Thompson (FEMS Microbiol Letters, 108: 175-82 (1993); claims 1-4, 7-10, 12, 19-24, 26-27 and 30-33), Simon (U.S. Patent No. 5,178,859; claims 1-4, 7-12, 19-24, 26-27 and 30-33) and Sesardic (WO 94/21684; claims 3, 4, 7-10, 12, 19-24, 26-27, and 30-33). The applicants' Amendment of September 5, 2001, the substance of which is repeated in the attached Second Amendment Under Rule 116 because a response to the previous Amendment has not yet been received, place the polypeptide claims in condition for allowance over the cited art, for the reasons described therein.

That is, upon entry of the attached amendments, the polypeptides of the claimed invention make a contribution over the art.

The Decision states that:

“... PCT Rules allow review of any Unity or Lack of Unity holding at each stage of prosecution. The determination may, therefore, change with each Office action depending on the prior art discovered and the applicant's actions. Such is no different from restriction practice in regularly filed applications where the examiner reviews the restriction requirement for correctness with each Office action.” See, page 3 of the Decision.

Accordingly, it is the applicants understanding that the basis of the restriction requirement was a belief by the Examiner, and the Director of Technology Center 1600 (i.e., Jasemine C. Chambers), that the restriction requirement was proper between the polypeptides and the DNA encoding the polypeptide because the elected subject matter (i.e., polypeptides), as defined by the claims pending at the time of the restriction requirement, allegedly failed to make a contribution over the prior art. It is also the applicants understanding that the “correctness” of the restriction requirement is reviewed “with each Office action”.¹

The claims of the elected Group have been amended in the attached Amendment to define over the art, as described below, to advance prosecution. The elected polypeptides, as defined in the claims, are therefore submitted to define a special technical feature in common with the subject matter of the Examiner's Group II (i.e., DNA encoding the polypeptides). The non-elected claims have been similarly amended, to advance prosecution. The Commissioner is requested therefore to have

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the attached Amendment entered, review and reconsider the Decision and restriction requirement for correctness, have the restriction requirement withdrawn and have all of the claimed subject matter considered on the merits.

Reconsideration and grant of the applicants Petition to withdraw the restriction requirement are requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____


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¹ Clarification is requested in the event that the applicants have not understood the Patent Office position stated in the Decision.